PUBLIC HEALTH COUNCIL

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Wednesday, July 9, 2008, 9:00 a.m., at the Department of Public Health, 250 Washington St., Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair John Auerbach, Commissioner, Department of Public Health, Mr. Harold Cox, Dr. John Cunningham, Mr. Paul J. Lanzikos, Mr. Denis Leary, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Mr. Albert Sherman, Dr. Michael Wong, Dr. Alan C. Woodward and Dr. Barry S. Zuckerman. Ms. Caulton-Harris, Dr. Michèle David, Dr. Muriel Gillick, and Dr. Meredith Rosenthal, were absent. Also in attendance was Attorney Donna Levin, DPH General Counsel.

Chair Auerbach announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance. He said further that first we would hear out of order testimony from State Senator Edward Augustus, Jr., and State Representative James O'Day on the Planned Parenthood Application:

Partial Testimony of Senator Edward Augustus, Jr. on the Planned Parenthood Application:

"...As the State Senator representing the Second Worcester District which includes 40 percent of the City of Worcester, I want to offer my strong support for the pending Determination of Need. Planned Parenthood's Worcester Health Center fills an important need in our community. The city's poverty rates are higher than that of the state average. Thirty-six percent of Worcester's residents live below 200 percent of the federal poverty level versus 22 percent of all state residents. In Worcester County women of child-bearing age are particularly vulnerable. Forty-one percent of women living below the poverty level are between the ages of 15 and 44. In addition, nearly one-third of women in Worcester County, who are in need of contraceptive services and supplies, live below 250 percent of the federal poverty level. Worcester residents also contract sexually transmitted infections at higher rates than overall state residents. For example, the rate of gonorrhea at a 50 percent higher rate than their peers across the state and face a 45 percent higher rate of Chlamydia infection. The new rate of newly diagnosed AIDS cases in Worcester is 50 percent higher than the state average. Although teen pregnancy rates have been declining across the state, Worcester still faces higher than average teen birth rates. 10 percent of births in Worcester are to adolescent mothers, a rate almost twice that of the state average."

Senator Augustus said further, "Planned Parenthood is the only healthcare provider in Worcester focused solely on sexual health. Although there are other community health centers that include sexual health as part of their services, none have the comprehensive approach that makes them unique, providing healthcare, sexuality education and advocacy for policy changes that improve women's health."

In conclusion, he said, "Lastly, Planned Parenthood's center currently on Lincoln Street in Worcester had over 10,000 consultations last year. That location is overcrowded. The parking is virtually non-existent. Because of the security issues necessary, it really doesn't provide for easy access to clients. That's why this new larger facility, which will be 11,000 square feet, has ample parking, will provide for the safety of its clients, and their architectural designs include green elements that will make it a great addition to the community as well as being environmentally progressive. I certainly would urge the Council to act favorably on this and appreciate the opportunity to testify."

Partial Testimony of State Representative James O'Day on the Planned Parenthood Application:

"…I represent the Worcester 14th District, which currently Planned Parenthood lies within at its Lincoln Street site. Prior to my becoming a state representative, I was a social worker for the Department of Social Services for 25 years, and I can certainly speak from a number of different vantage points to the really essential need for the services that Planned Parenthood provides to the families in the City of Worcester and the surrounding neighborhood – neighbors, I should say.

He continued "The fact that we now have to move Planned Parenthood from its Lincoln Street site to its Pleasant Street site is really borne out of the efficiency in which they do their work and the many clients that they service, and as the good Senator has indicated, they have really outgrown their current location. Just as a sidebar, I am also happy to report that that current location is going to be utilized by Great Brook Valley Health Center, so we are really sort of getting a two-for one here, where the Great Brook Valley Health Center is going to be able to expand a little bit into the Lincoln Street site and now that we are going to hopefully have a state of the art, high quality reproductive health center at the Pleasant Street site. I think that particular site is far more central, not only to Worcester citizens but those from Central Massachusetts. So the services that Planned Parenthood provides to not only our teenagers, but our families in general, again the need is essential, and I believe it's been spoken to for the past 20 plus years in the City of Worcester, and I strongly support the relocation and the continuation of the services that Planned Parenthood provides."

Chair Auerbach thanked the legislators and proceeded with the regular agenda.

Testimony by Dr. JudyAnn Bigby, Secretary of the Executive Office of Health and Human Services on Determination of Need Regulation Amendments:

Chair Auerbach made introductory remarks, "Dr. Bigby has provided the state and the Department of Public Health with leadership in terms of our thinking about the priorities that need to be established in this era of healthcare reform, as we think about the ways to maximize healthcare quality and limit cost, and she has helped us in terms of thinking about some of the ways that the Determination of Need process can be useful as we address some of those larger issues..."

Dr. Bigby stated in part, "...The reason I am here today is because I think that this change in the regulations that you are going to consider today are very important in a larger agenda that we have for the Commonwealth. In many ways, the state is looking for a way to have a better rational health planning process, and in many ways, the Public Health Council helps to serve in that role, and your oversight of the DoN process is very important from that perspective. We know that we have a lot of challenges in front of us. We have a lot of successes as well in healthcare reform and improving access to care, but we want to maintain those successes and so the work that we do going forward will help us to do that."

She continued, "Our overall goals really are to make sure that individuals can be healthy and that communities can be healthy, and that is the bottom line that we are really most interested in. I want to say that I support the change in the regulations that are coming before you today. I think they make an important first step toward making sure that our system is more rational. I think that the changes will help level the playing field in terms of supporting community hospitals and acknowledging the important contributions that they make to our healthcare system..."

Dr. Bigby further noted that she approved of the following proposed regulatory changes in today's proposed regulations: the inpatient satellite projects being under the purview of the DoN process and the changes related to physician exemption letters that eliminates the loophole allowing for unregulated acquisition of new technologies.

In closing Dr. Bigby said, "...For me the bottom line is that we have healthy people in healthy communities and we can't to that if we don't have a rational way to determine where the services are..."

FINAL REGULATIONS:

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO DETERMINATION OF NEED REGULATIONS – 105 CMR 100.000 ET SEQ. (ORIGINAL LICENSURE OF HOSPITALS, PHYSICIAN EXEMPTION LETTERS AND SECTION 308 EXEMPTION REQUIREMENTS):

Ms. Joan Gorga, Director, Determination or Need Program, presented the proposed regulations to the Determination of Need Program, accompanied by Dr. Paul Dreyer, Director, Bureau of Health Care Safety and Quality, and Attorney Carol Balulescu, Deputy General Counsel, Office of the General Counsel. It was noted for the record that Attorney Melissa Lopes, Deputy General Counsel, Office of the General Counsel, also worked on the DoN amendments.

Ms. Gorga stated in part, "...I'm going to be discussing with you this morning the proposed amendments to the Determination of Need Program. You released these for a public comment period several months ago. We did have a public hearing on them, and just under 30 people testified, 30 people attended and about 14 people testified...We received more testimony on the physician exemption letters, the grandfathered letters, than on any other element. The proposed amendments would eliminate and put an end to the grandfathered letters. There would be no new technology without DoN Review. This assures a level playing field and reduced costs, and we heard from many hospitals who indicated that they were unable to do their planning when there was this specter of these grandfathered letters that might be implemented at any time on the next street corner, so it was important for us to eliminate the grandfathered letters. The second item, which we heard a lot of testimony on, was the satellite inpatient beds, and with these proposed amendments, we put in place a thorough public process for new facilities, and in many cases, this involves the teaching hospital expanding into markets previously served by the community hospitals...The third item that we modified with these is the .308 process allowing it to grant MRI approvals mostly to community hospitals. The .308 process for MRIs will now include community initiatives, and there will be no need for the facilities to submit a full DoN within a year, since in most cases these were unable to be reviewed. The fourth item is the build-out of shell space. As you have seen in the major capital expenditure projects, shell space is popular. It is an economic means to further expansion; building with today's cheaper dollars...that request is now a significant change. In the compliance or post-DoN process for the projects after they are approved, there are three types

of compliance projects, immaterial change, minor change, and significant change. Minor and immaterial do not come before the Council. Significant changes in most cases come before the Council, particularly if it is a project that you originally reviewed so by placing shell space in the significant change category, these are projects that will come before you…"

Ms. Gorga's presentation continued on the public comments. Please see the Staff's memorandum to the Council dated July 9, 2008 which has the summarized comments attached, along with the proposed regulations. Some of the comment highlights are:

- Revised original proposed regulations on the physician exemption letters by changing the completion date to July 1, 2009, requiring substantial and continuing progress on these projects by September 1, 2008 and full implementation (treating patients) by July 1, 2009;

- An oversight in original proposal was fixed by including transfer of site in the list of events mandated for review related to physician exemption letters;

- Clarified phrase, "inpatient services" for unit of a health facility that will be off site at an inpatient satellite;

- Added community initiatives provision in the .308 process and eliminated the requirement that the applicant hand in an application within a year;

- Eliminated the suggestion of a new Factor 10 by instead strengthening Factor 1 – replaced the word "should" with the word "must" so that it is now a requirement that they report on a possible duplication of services in the applicant's area.

It was noted that in general the comments received on the DoN amendments were positive and further that the amendments were needed since it has been about 20 years since they were last updated. Discussion followed by the Council. Council Member Mr. Paul Lanzikos inquired about the Community Health Initiative Funds and Mr. Geoff Wilkinson addressed the Council and explained the evaluation process he was leading on the Community Health Initiative Funds. Mr. Wilkinson noted that in seven years, the Community Health Initiatives Contributions by DoN Applicants' total $60 million dollars, some of them still in the pipeline. DPH staff with help from a consultant and the DoN staff are in the process of setting up an "Access software" database so that staff can do an analysis of how the money has been allocated, where it is being spent and assess which projects are underway and which are not yet implemented.

Mr. Wilkinson further noted that within 90 days he will have a report for the Public Health Council on the matter. He also noted that they are developing standard protocols for applicants so that DPH has clear and consistent standard procedures and protocols for the Community Health Initiative Contributions. Mr. Lanzikos added for the record, "...I believe the Public Health Council does have an appropriate role to be proactive in helping set or at least affirm the goals and objectives that are associated with the Community Health Initiatives. I would like to see a closer working relationship between the Public Health Council and the Office that's responsible for the administration of the Community Health Initiatives. We look forward to that communication."

Dr. Woodward applauded the rewrite of the DoN regulations, noted that he "believes it is an uneven playing field and that we are driving healthcare to more costly environments and actually leaving communities without local access to quality care and believes the amendments will help level the playing field". Dr. Woodward said in regards to deleting the proposed Factor 10, "I would say that language in Factor 1 is much diluted relative to what was proposed in 10, and I particularly wonder about the word "unnecessarily", because I think it is very nebulous and I am wondering whether we should just strike that word...I would like comment back and thoughts about whether we can put a stronger word or eliminate that word."

Dr. Paul Dreyer, Director, Bureau of Health Care Safety and Quality responded, "...The reason we were willing to abandon Factor 10 was we thought that the substance was essentially covered in Factor 1, and so in that spirit, I don't think we would have a problem substantively with removing the word 'unnecessarily'..." Attorney Carol Balulescu, Deputy General Counsel added, "I don't think there is an issue procedurally, because we had proposed the Factor 10, so certainly regulated parties were on notice that we were considering such a change." Chair Auerbach added in part, "...When we get to the vote, we will be voting on that sentence without the word 'unnecessarily'."

Mr. Harold Cox asked in part, "...How do we evaluate the recommendations the staff give, how do we actually think about this in terms of the kinds of things that Secretary Bigby was presenting to us and thinking about how this process impacts what happens to healthcare delivery in the state?..."

Chair Auerbach responded and said in part, "...It sounds like you are suggesting that perhaps we have additional forums, where before we get to the stage of asking staff to translate some ideas or principles into specific proposals, we may want to spend more time as Council Members discussing the issues themselves and coming up with recommendations that are generated initially in the Council

discussion?" Mr. Cox replied, "That's correct but also it is also a matter of looking at what is the right way to evaluate the material that put in front of us?"

Dr. Woodward concurred with Mr. Cox's suggestion that the Council have the larger discussion about "how do we optimize healthcare delivery in this state and what role does the Council play in that discussion and it may not be related to a specific DoN process..." Chair Auerbach agreed to have discussions about the "larger issues particularly the ones that impact the health of the communities and the residents..."

Mr. Paul Lanzikos agreed with Mr. Cox and added further, "I would put forward the Community Health Initiatives. It might be a good opportunity to exercise this different approach. Rather than having sort of a finished product coming to us and giving a yea or nay, do we understand that we could be a little bit more involved in the formative process. When I hear that $60 million of investment has been involved here, that's a fairly significant amount of money that affects a lot of health policy in a very real way, and I think in the spirit of what Harold just said, this would be a good opportunity for us to try that process."

Chair Auerbach stated in part, "We will do our best to come up with some recommendations for how we might achieve the kind of discussion and process that you are suggesting and appreciate the suggestion that a place to start might be looking at that upcoming discussion on Community Health Initiatives."

Dr. Alan Woodward made the motion for approval with his amendment to remove the word "unnecessarily" from the Proposed DoN Regulations under 105 CMR 100.533 (B), page 47, second to last line. After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Final Promulgation of Amendments to the Determination of Need Regulations – 105 CMR 100.000 et seq. (original licensure of hospitals, physician exemption letters and section .308 exemption requirements).** A copy of the approved amendments and attachments are attached and made a part of this record as **Exhibit No. 14,904.**

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO REGULATIONS – 105 CMR 700.000 CONCERNING THE PRESCRIPTION MONITORING PROGRAM:

Dr. Grant Carrow, Director of Drug Control Program and Deputy Director, Bureau of Health Care Safety and Control presented the proposed amendments to 105 CMR 700.000 to the Council, accompanied by Dr. Paul Dreyer, Director of the Bureau and also Deputy General Counsel, Howard Saxner, Office of the General Counsel.

Dr. Carrow stated, “We come before the Council to request final promulgation of proposed amendments to regulations governing the Department’s Prescription Monitoring Program as the Commissioner just described. The Drug Control Program presented the proposal to the Council at its March 12 meeting and held a public hearing on April 25, 2008. As we discussed in March and just for a brief review, the main purpose of the proposed amendments is to enhance the Prescription Monitoring Program to serve as a clinical tool, in addition to its current role as a public safety tool. This would be accomplished by enabling the program to share information with a prescriber when the program identifies possible abuse or diversion of schedule II prescriptions by a patient. Disclosure of information would be based on guidelines developed in consultation with the program’s Medical Review Group and the Prescription Monitoring Program Advisory Board, which consists of practitioners as well as other interested parties. Disclosure would be for the purpose of assisting a practitioner or a pharmacy in assessing a patient, and a practitioner or pharmacy would not be required to take any specific action with respect to the information provided. The program would approach implementation of these provisions with small scale pilots to determine the best practices for utilization of reports.”

Dr. Carrow continued, “Those receiving a report would also be provided with a tool kit, including information on interpretation and use of the data, as well as resources for managing patients identified to be at risk for or involved in prescription drug abuse or diversion. Other provisions in the amendment include requiring pharmacies to report additional data fields to the program, which is a prerequisite for sharing the information with practitioners, and pharmacies as well as a means to increase the utility of the database. An additional provision would change the current customer identification provision from a requirement that a pharmacist make a good faith effort to verify an ID and change that to a requirement that the ID actually be obtained. The amendments include provisions that would ensure that a patient is not unreasonably denied access to needed medication simply due to lack of an ID. The April public hearing resulted in testimony from one individual and three organizations, and in addition, we received comments and suggestions from two state agencies, so I will review that as the Commissioner requested. The major comments received and staff responses are tabulated in the memo in Attachment B. Some of the testimony recommended broad access to the database by prescribers. Such a program is beyond the scope of this initiative. However, the proposed amendments before you will provide a foundation on which such a program would be considered by the Department, by the Council in the future. Pharmacy and pharmacist organizations raised questions about operational details of implementation of the amendments. Staff has been working with organizations, particularly the National Association of Chain Drugstores, to address these operational issues. We believe that the issues have been clarified…The Executive Office of Health and Human Services

recommended that the regulations be amended to permit release of program data after Medical Review Group and DPH review and approval to EOHHS for the purpose of identifying suspected fraud and abuse of the MassHealth program. The Department currently and will continue to provide information on suspected cases of fraud and abuse of the MassHealth program to the Office of the Attorney General. Nevertheless, staff agrees with the recommendation to add the MassHealth program as a recipient of information and have amended the proposal regulation accordingly. In the future, the Department will work closely with both agencies with respect to Medicaid fraud."

He continued, "The Attorney General raised concerns regarding access to PMP information for law enforcement purposes. The Medical Review Group and Department have worked in the past with the Attorney General on policies to expedite responses to requests from the Attorney General and other law enforcement agencies for information, and staff are prepared to meet with the Attorney General to further explore the means by which the review processes might be improved as well as to examine alternatives for addressing the Attorney General's concerns. These proposed amendments would set forth the requirements for clinic and the hospital pharmacies. The amendments do not apply to medication orders for inpatients. The Board of Registration in Pharmacy would in turn need to promulgate companion amendments to set forth the same requirements for community pharmacies."

In closing, Mr. Carrow said in part, "Staff feels that the amendments proposed here are a critical step in addressing the serious and growing problem of prescription drug misuse and abuse. Staff has also made some technical changes in response to issues in the public testimony. We request Council approval…"

Discussion followed by the Council. Dr. Michael Wong noted as a physician he has experienced patient doctor shopping and asked, "…Will there be the opportunity for real time access, such as for the physician or the house officer who's rotating through an emergency room and a patient comes in requesting refill of pain medications because of chronic pain issues and no access to a medical record to either confirm that a primary has already written for that or provided the medication?"

Dr. Carrow responded in part, "…That is certainly the practice in some other states with their Prescription Monitoring Programs. It is not part of the current initiative. That is a large expansion of the Prescription Monitoring Program which is not envisioned at this time….The program that you are describing carries a large cost with it, and that would have to be one of the issues that would have to be dealt with, as well as the privacy concerns that have been raised at this Council and elsewhere…there is a difficult balance that the program is constantly

dealing with in terms of balancing the needs of prescribers, law enforcement, and privacy for patients."

Dr. Wong said he appreciated the privacy concerns..."But if this is going to be one of those tools where we can really make a big impact or try to make an impact with regards to substance abuse interventions...that some kind of secured access or even secured phone line using our Massachusetts DEA numbers...might be one way of starting as a suggestion."

Dr. Woodward agreed with Dr. Wong about the substance abuse interventions and said in part, "...I would request that we look at what that cost might be and how we might potentially fund this...my suspicion is it would more than pay for itself in the negative financial impacts of drug diversion and dependency."

Dr. Carrow responded, "We welcome that discussion and we certainly think that in the context of the earlier discussion, a broader discussion of the role of the Prescription Monitoring Program and how it can best serve the Commonwealth and the users of the system would be terrific." Dr. Carrow noted that in the state of Kentucky which has such a program and it is held out as the gold standard, received $5 million to establish their program and the Massachusetts program is funded at under $300,000. It was further noted that Kentucky's operating costs are in the millions.

Chair Auerbach summarized in part, "...The Department will commit to coming back with reexamination of the potential for addressing a number of different concerns with regard to the Prescription Monitoring Program...Keeping Dean Cox's comments in mind, perhaps we will try to frame this in this larger discussion what is the potential for the use of monitoring programs in the larger sense and what's the benefits in terms of the overall health of residents in the Commonwealth and think about creative alternatives...We definitely will address the issue of what other states are doing...We will ask staff to do research in the areas that have been mentioned specifically start-up and annualized cost and indicators of efficacy in terms of improving health, particularly addressing drug treatment issues in an effective manner." Chair Auerbach further noted that they are in discussions with the state Attorney General's Office about access of information for them and others in the criminal justice and judicial systems that may or may not require Council action in the future.

Council Member Mr. José Raphael Rivera inquired about how the practitioners could connect with the services and further asked Dr. Carrow to keep "living resources such as community health workers in the loop". Dr. Carrow responded by stating, "We have been working with practitioners to understand how to interpret the data, how to best utilize it, and how to find resources to manage patients who may be at risk or actually involved in drug diversion." He

added further that they would pilot test the tool kit and the reports with selected providers to determine that they have the best practice to do that. It was noted that the Prescription Monitoring Program has an Advisory Board that consists of a broad range of healthcare providers and other interested parties that will review all of the implementation steps and that Dr. James Wechler, who attended the March Public Health Council Meeting was their first pilot subject.

Council Member Michael Wong recommended that some hospital training programs and house staff and medical practitioners be included in a pilot program. Chair Auerbach confirmed that a hospital-based practice would be included in the pilot program. Dr. Alan Woodward added two suggestions (1) that "it would be useful to think about a database of resources for evaluation and treatment, chronic pain centers and dependency centers that practitioners could access, to identify local resources that would be available to their patients; and (2) that the Department could reach virtually all physicians in Massachusetts through the "Vital Signs" Publication – it would be useful as an informational educational interface as the Department rolls out this program."

Council Member Albert Sherman moved approval of the Amendments. After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Final Promulgation of Amendments to Regulations – 105 CMR 700.000 Concerning the Prescription Monitoring Program**. A copy of the approved amendments are attached and made a part of this record as **Exhibit Number 14, 905**.

REQUEST FOR FINAL PROMULGATION OF AMENDMENTS TO THE REPORTABLE DISEASES, SURVEILLANCE, AND ISOLATION AND QUARANTINE REQUIREMENTS – 105 CMR 300.000:

Dr. Alfred DeMaria, Director, Bureau of Communicable Disease Control, together with Ms. Gillian Haney, Director, Office of Integrated Surveillance and Informatics Services, and Attorney Susan Stein, First Deputy General Counsel, Department of Public Health, presented the proposed amendments to 105 CMR 300.000 to the Council.

Dr. Alfred DeMaria said, "...We were here on April 9 with proposed amendments to 105 CMR 300.000, the Disease Reporting Surveillance and Isolation and Quarantine Requirements, and basically proposing some updated wording, some updated procedures, as well as additional diseases on the list and some clarification of procedures around the actual implementation of isolation and quarantine. And those amended regulations incorporated Dr. Wong's careful and valuable review recommendations..." Ms. Haney will review the specifics of the public comments."

Ms. Gillian Haney noted that the public hearings had been held on May 27, 2008 in Shrewsbury and on June 2 in Jamaica Plain at the Hinton State Laboratory Institute. No oral testimony was received nor any written testimony during the comment period. After this time, three comments were received from DPH staff which resulted in changes to the proposed amendments:

1. A request from the State Public Health Veterinarian to add lymphocytic choriomeningitis virus to the list of reportable diseases was adopted. The corresponding section outlining Isolation and Quarantine Requirements for this disease was also updated.

2. Mycobacterium tuberculosis was inadvertently left off, and has now been added to, the list of organisms to be submitted to the State Laboratory Institute for further testing (300.172: Submission of Selected Isolates and Diagnostic Specimens to the Hinton State Laboratory Institute).

3. Minor amendments were made to section 300.210: Procedures for Isolation and Quarantine to provide additional clarity.

In summary, Ms. Haney said, "We are proposing several substantive amendments to the regulations. The first requires that several diseases be added to the list of diseases reportable by healthcare providers in laboratories and these are listed in your packets that were provided for you. We are proposing adding these lists to the diseases reportable to local boards of Health and the Department and have amended the relevant sections on isolation and quarantine requirements to include the most recent recommendations from the Centers for Disease Control and Prevention for cases and suspect cases of individuals with these diseases. We are also recommending that healthcare providers report pediatric deaths due to influenza and any illness believed to be due to novel influenza viruses. The third proposed amendment is a new section under 172, which specifies which isolates and diagnostic specimens shall be submitted to the Department for further examination. Those organisms are also specified in the packets provided to you. In addition, we have added a new requirement that all laboratories report notifiable conditions through secure electronic mechanisms to the Department so we can act in a more timely and complete manner for follow-up of those diseases. The final proposed amendment is also a new section under 310, which are procedures for isolation and quarantine and they outline the specific legal requirements that are necessary to implement isolation and/or quarantine. These procedures are mandatory for DPH but are only encouraged for local Boards of Health because local Boards of Health have the independent authority to issue their own regulations. We request that the Public Health Council approve the amended

regulations." Dr. DeMaria noted for the record that the regulations are under constant review involving major stakeholders, in particular, by the local boards of health and reporting sources so much of the work is done in advance of the public hearing/comment process.

Chair Auerbach noted for the record, "I think it is a credit to you both and to Dr. Wong for his able and I might say unpaid assistance in terms of reviewing the regulations that there weren't any comments, and I think that really reflected that people were supportive of them and saw them as necessary in order to update our regulations..."

After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Final Promulgation of Amendments to the Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements – 105 CMR 300.000.** A copy of the approved amendments and memorandum to the Council dated July 9, 2008 is attached and made a part of this record as **Exhibit Number 14, 906**.

Brief Update on Tomato Salmonella Outbreak:

At Mr. Sherman's request, Dr. DeMaria briefed the Council on the tomato salmonella outbreak. He said in part, "There's a major outbreak of Salmonella St. Paul going out in the United States (900 cases so far) but I think it is important to recognize that that's actually a small proportion of all the Salmonella cases that get reported in the US each year, especially at this time of year, because we tend to peak in the summer in terms of salmonellas.

He said further, "...Initial investigation strongly suggested a correlation with the ingestion of tomatoes, in particular Roma tomatoes and round tomatoes. This is undergoing a current review and the direction it's going in is more towards essentially condiments and additives, in particular jalapeno, Serrano peppers and cilantro – it is a revolving story as more information is acquired and more intensive control studies conducted to try to get exactly what the source of the salmonella is..."

DETERMINATION OF NEED PROGRAM: CATEGORY 2 APPLICATION: PROJECT APPLICATION NO. 2-4931 OF PLANNED PARENTHOOD LEAGUE OF MASSACHUSETTS D/B/A PLANNED PARENTHOOD OF CENTRAL MASSACHUSETTS for new construction to replace and relocate the existing satellite clinic/ambulatory surgery center in Worcester:

Note: Council Member Rivera recused himself from discussion and voting on this application.

Mr. Jere Page, Senior Program Analyst, Determination of Need Program, presented the application to the Council. He stated, "...Planned Parenthood is seeking approval for new construction to replace and relocate the existing satellite clinical/ambulatory surgery center from 631 Lincoln Street in Worcester to a new site at 470 Pleasant Street in Worcester. The need to replace and relocate the existing facility is based on several factors, which mainly involve a number of physical deficiencies in the existing facility that adversely affect Planned Parenthood's ability to provide services at the highest quality and efficiency. There is also a lack of adequate security at the existing clinic, as well as safe parking and a lack of public transportation at the clinic. The proposed new facility on Pleasant Street will employ a significantly enhanced design which will allow patients to receive the majority of their services in one room, without the need to move from one room to the next, and it will also provide much more effective security for patients and staff. The recommended maximum capital expenditure is $6,196,653. This will be financed to an equity contribution of $1.7 million from available funds and the remaining MCE of $4.4 million will be financed by tax-exempt bonds issued by the Mass. Development Finance Authority at an anticipated fixed interest rate of 3.5 percent for a 25-year term."

Mr. Page continued, "With regard to Community Health Initiatives, Planned Parenthood has agreed to provide a total of $309,833 over a maximum of seven years or $44,262 per year for programs to provide primary and preventive healthcare services to underserved populations in the Worcester area. Please note, also that the Roderick Murphy Ten Taxpayer (TTG) registered in opposition to the proposed project and requested a public hearing which was held on May 13, 2008 in Worcester. The hearing was attended by about 100 people, 28 of whom testified. The TTG asserted that Planned Parenthood does not provide adequate healthcare and therefore, its DoN application to move to a new location should be denied and its license to operate cancelled by the Department. "Staff is recommending approval of this project with the conditions indicated on page 13 and 14 of the staff summary."

Discussion followed by the Council. Mr. Paul Lanzikos, Council Member had a couple of questions, "...To whom does the annual evaluation of the Community Initiative Mini grants money go?" Ms. Cathy O'Connor, Director, Office of Healthy Communities at DPH stated that it is customary for the evaluations to be submitted to her office. In addition, she added, "We usually share it so the whole idea is to create accountability and visibility." And Mr. Lanzikos asked about an entry on page 12 of the staff summary, "three individuals identified as Massachusetts residents each provided derogatory comments but the individuals were not identified by staff?" Mr. Page replied that staff customarily does not identify anyone but the leader of the TTG, but that the information is public record on file at the DoN office. This was discussed and it was decided that DoN

Staff should in the future identify the commenter in future staff summaries and supporting documents.

Discussion continued and Dr. Woodward inquired about the multipurpose room and security of Planned Parenthood.

Ms. Diane Luby, President of Planned Parenthood League of Massachusetts, the applicant addressed the Council. She said in part, "...PPLM is celebrating our 80 anniversary this year, and so we have been very proud to be the leading proponent of family planning services in the Commonwealth for these last 80 years. As was stated, we opened our Central Mass. Health Center in 1982. It was the first location where we began delivering healthcare services. We are thrilled that we will be constructing our first green health center 26 years later, a first for us and a first again in Worcester...We understand that DPH is advocating for green building standards for healthcare facilities and so we are happy to be ahead of the curve on this. We commend the staff on the thorough review and understanding of the combination of facility, space, efficiency, and security issues, along with the parking challenges for both our staff and patients and the poor access we have in our current location to public transportation. This led us to the planning process and the conclusion that we had to relocate. We look forward to the opportunity to improve our patient experience, both from a quality and efficiency standpoint, with this new one-room design. .... I respectfully ask that the Council approve our DoN application so that we can continue to provide exceptional sexual and reproductive health services in central Massachusetts and I thank you for your consideration, and I would be happy to answer Dr. Woodward's comment about security."

Ms. Luby answered the security question, "...One of the things in selecting our architectural firm was we were stunned with the technology in looking at this building, because we actually had, through the benefit of the software they were using, the ability to look at placement of the new building in several ways on the lot and which way we could adequately address security. The building lot that we purchased actually has two entrances and by the way the building has been designed, we will actually block off the front entrance and then the back entrance is far enough away so that when protesters are there, they won't actually be interfering with the patients when they are getting out of their car. We have also designed it so that the building is up on stilts. The security office will be on the lower level and so we will really have adequate right-of-the way in the parking space but only have one place where protesters could be, which is out of the site."

Discussion continued by the Council, please see verbatim transcript for full discussion. Mr. Denis Leary, Council Member asked if the project was new construction or renovation of an existing building. Ms. Luby said that they will be

knocking down the current structurally unsound old building and replacing it with a new one. Dr. Woodward asked if the building would be LEED certified. Ms. Luby replied that it would not be a LEED certified building because they would rather put the money into patient services. Council Member Albert Sherman suggested that Ms. Luby contact Lieutenant Detective William McDermott, Chief of Detectives' of the Brookline Police Department at 617-735-2222 for security recommendations.

Council Member Dr. Michael Wong made the motion to approve the application. After consideration, upon motion made and duly seconded, it was voted unanimously to approve **Project Application No. 2-4931 of Planned Parenthood League of Massachusetts d/b/a Planned Parenthood of Central Massachusetts**, with a maximum capital expenditure of $6,196,653 (February 2008 dollars) and first year incremental operating costs of $263,376 (February 2008 dollars). A staff summary is attached and made a part of this record as **Exhibit No. 14,907.** As approved, the application provides for new construction to replace and relocate the existing satellite clinic/ambulatory surgery center in Worcester, from 631 Lincoln Street to a new site at 470 Pleasant Street in Worcester. This Determination is subject to the following conditions:

1. Planned Parenthood shall accept the maximum capital expenditure of $6,196,653 (February 2008 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and .752.

2. The total gross square feet ("GSF") for this project shall be a total of 10,886 GSF to replace and relocate the existing clinical facility.

3. Planned Parenthood shall contribute 29% in equity ($1,789,361 in February 2008 dollars) to the final approved MCE.

4. Planned Parenthood shall obtain Medicare certification for its ambulatory surgery center within one year of licensure of the new Worcester satellite facility.

5. For Massachusetts residents, Planned Parenthood shall not consider ability to pay or insurance status in selecting or scheduling patients for medical or surgery services, and shall assure that racial and ethnic minorities, handicapped, and other underserved populations have access to its services.

6. Planned Parenthood has agreed to provide a total of $309,833 (February 2008 dollars) over a maximum of seven years to fund the community health service initiatives described previously in Section H: Community

Health Initiatives.

7. With regards to its interpreter service, Planned Parenthood shall:

    a. Identify a coordinator of interpreter services to ensure optimal, timely and competent medical interpretation;
    b. Post signage at all points of contact and public points of entry informing patients of the availability of interpreter services;
    c. Obtain the patient language preference prior to patient visits;
    d. Establish a reliable and valid system to schedule interpreting session, track requests, monitor completed interpreting sessions;
    e. Provide information to patients on the availability of interpreter services at no cost;
    f. Use only trained interpreters to provide medical interpretation and/or logistical support;
    g. Prohibit the use of minors to provide interpreter services;
    h. Discourage the use of patient family and friends as medical interpreters;
    i. Assess the quality of staff who function as trained interpreters to ensure the quality and competence of interpreters provided through contracted vendors;
    j. Develop a detailed plan for training, clinical, support and administrative staff on the appropriate use of interpreters;
    k. Complete a yearly Language Needs Assessment (LNA) [Guiding principles developed by OHE are a recommended source];
    l. Ensure timely, accurate, competent, and culturally appropriate patient educational materials, and include LEP patients in any satisfaction survey.

Planned Parenthood shall submit a plan to address these interpreter service elements to OHE within 120 days of the DoN approval. In addition, Planned Parenthood shall notify OHE of any substantial changes to its Interpreter Services Program, and progress reports shall be submitted annually to OHE within 45 days of the end of the federal fiscal year. Also, Planned Parenthood shall follow recommended National Standards for Culturally and Linguistically Appropriate Services ("CLAS") in Health care.

Staff's recommendation was based on the following findings:

1. Planned Parenthood is proposing new construction to replace and relocate its existing clinic facility from 631 Lincoln Street in Worcester to a new site at 470 Pleasant Street in Worcester.

2. The health planning process for the project was satisfactory.

3. The proposed relocation and replacement of Planned Parenthood's existing satellite clinic/ambulatory surgery center in Worcester is supported by current and projected utilization, and need for security as discussed under the Health Care Requirements factor of the Staff Summary.

4. The project, with adherence to a certain condition, meets the operational objectives factor of the DoN Regulations.

5. The project, with adherence to a certain condition, meets the standards compliance factor of the DoN Regulations.

6. The recommended maximum capital expenditure of $6,196,653 (February 2008 dollars) is reasonable compared to similar, previously approved projects.

7. The recommended operating costs of $263,376 (February 2008 dollars) are reasonable compared to similar, previously approved projects.

8. The project is financially feasible and within the financial capability of the applicant.

9. The project meets the relative merit requirements of the DoN Regulations.

10. The Roderick P. Murphy Ten Taxpayer Group (TTG) registered in opposition to the proposed project and requested a public hearing, which was held on May 13 in Worcester.

For the record, State Senator Harriett L. Chandler arrived during the occupational health presentation; however, the presentation was put on hold so her testimony could be heard before the Council on the Planned Parenthood application. Upon her arrival Chair Auerbach said in part, "…We know you have strong feelings about the application that was under consideration today for Planned Parenthood of Central Massachusetts, and I think you will be happy to hear that we did vote the way you would have recommended…"

Senator Chandler stated, "…I represent the First Worcester District in the Massachusetts State Senate, and I was here to talk about the Determination of Need for the Planned Parenthood League of Massachusetts relocation plan in Worcester. It is a very critical issue to me. I was not able to testify at the hearing. We were in session when you had the hearing in Worcester, so I felt that I had to make every effort and I took you literally when you said it was from

9:00 a.m. to 12:00 p.m.....I should have realized that it might have been one of your first issues on your agenda. I am really here to commend you on what you already voted on and perhaps give a little bit more reason for the decision you have already made."

Senator Chandler continued, "For 80 years, Planned Parenthood has been the state's leading provider of sexual and reproductive health services and they have a long history of providing essential services in the City of Worcester. I recently was a lead sponsor on the Buffer Zone Bill, so that I spent some time in the Planned Parenthood facility in Worcester and I know exactly the problems that the Planned Parenthood facility has in its present location. It has every reason to move. It has lack of security. It is not able to protect the privacy or the confidentiality or even the persons of the people who come to the agency. The present facility was founded in Worcester in 1982, so it is celebrating its 26th year, and it's become truly an institution in Worcester. It services over 10,000 patients a year in its Worcester location. So it's an important facility. It's not just important for reproductive services, but clearly it's also important because it provides much-needed health services to a large percentage of the population. In its current location, demand exceeds capacity. It wasn't built for this purpose and so this move will allow the Planned Parenthood to increase capacity and meet the growing demand for its services. In other words, it's been very successful, and what we were trying to say is, if you give that Determination of Need as you have, you are allowing it to meet the demand that we currently have in central Massachusetts for its services."

Senator Chandler stated further, "The new location is also centrally located and easily accessible to public transportation, which many of the patients who come really require that kind of facility. And the current health center is overcrowded, it's outdated, it's inefficient. It wasn't made for the purpose it serves, and hopefully all of these issues will be corrected in the new facility. There is not even enough clinical, administrative or storage space in the current facility. The design of the new facility will allow for improved patient comfort and privacy as well as more efficient clinical operations. And it is as a fundamental, privacy and safety of the patients and the staff are our priority. This will truly be able to be realized at the new location.... For all these reasons, and because there is such widespread support in Worcester, I commend you for the approval you have already given, and I thank you very much for allowing me to speak to you, out of order, and I thank the people whom I have basically interrupted here.... I thank you very much."

Chair Auerbach noted, "Thank you Senator Chandler. We noted your support for this earlier before the vote was taken and before the discussion took place, but thank you for your taking the time to come down here. I think it's an indication of your dedication to this issue and many other public health issues and we

appreciate your support on so many things." Council Member Mr. Paul Lanzikos asked that Senator Chandler's remarks be in the official record.

"COMBATING OCCUPATIONAL HEALTH DISPARITIES IN MASSACHUSETTS: FROM DATA TO ACTION" by Letitia Davis, ScD, EdM, Director, Occupational Health Surveillance Program, Department of Public Health and Marcy Goldstein-Gelb, Executive Director, Massachusetts Coalition for Occupational Safety and Health (MassCOSH):

Dr. Davis made a brief overview of the Department's Occupational Health Surveillance Program and in particular focused on racial and ethnic groups in Massachusetts and concluded with brief examples of translating their work into action. At one point she noted, "Now public health surveillance carries with it, I believe strongly, the imperative for action, the responsibility to act on the information that we obtain, and so we are actively involved and kind of using our data to target intervention and prevention efforts in this state. These range from interventions in individual work sites, broad-based outreach to workers and employers in targeted industries, and development of public health policies to reduce workplace health and safety risks. We even had some examples of successes in our past influencing equipment manufacturers so that the equipment that is used in our workplaces is safer than it was in the past..."

Dr. Davis noted further that they use a wide variety of data sources to track occupational injuries, work-related asthma, and work-related injuries to teens. They use large population data sects, such as hospital data, cancer registry data, the BRFSS data, OSHA logs for information, worker's compensation records, and conducted waiting room interviews of patients at community health centers.

She noted that, "...Workers are injured because there are hazards in the workplace that are preventable and we need to do a better job of controlling the hazards, and that's first and foremost...There are other factors that likely contribute to the risk such as racism, discrimination, language and literacy, long work hours and forced overtime, lack of health and safety training, low awareness of legal rights and resources, the burden of immigrant status and economic insecurity that may make workers hesitant to speak-up and to complain about health and safety issues."

Ms. Goldstein-Gelb, of MassCOSH addressed the Council. She said in part, "...We are a non-profit membership coalition comprising workers, health professionals, safety experts, unions and community groups that focus on worker health and safety, and in particular, we emphasize devoting resources to those that do bear that disproportionate burden that Dr. Davis was referring to, and in particular, immigrants, people of color, and young workers – teens...."

Ms. Goldstein-Gelb noted some of the activities they are involved with: They have a Worker's Center, a safe space for immigrant workers to be able to learn about the hazards in their workplace, identify them, know what their rights are, and then learn strategies for addressing them. The staff train immigrant workers to serve as leaders, and they, themselves, conduct the outreach. They serve as examples to other workers to overcome the enormous fears that they face in taking action to address hazards in their workplace. We have a network of attorneys who can also help in the event that in many cases they are actually legal violations that the workers are facing. We are able to use the trends that the occupational Health Surveillance Program tracks through its surveillance to use as teachable moments, to educate both workers and employers about what can prevent these injuries and accidents from taking place...and we work on policy initiatives....They train teens to do outreach and educate other youth about the child labor laws and about their rights on the job..."

In closing, she said, "In conclusion, I just want to highlight a few areas that I think are really critical in our partnership between the community and Department of Public Health. Again, we depend on the data that the Occupational Health Surveillance Program collects, so that we can focus on the greatest risks so that we can educate employers and identify policy needs. There's an enormous concern that the program needs to rely on grants that change from year to year and that there really needs to have that infrastructure and institutional support in order for the community to be able to benefit from us. Second, another sort of opportunity is that there are many vehicles that the Public Health Department uses to collect information, numerous surveys that go out that gather public health data. We believe that occupational health information can be easily integrated into this and needs to be remembered and not sort of a step-child, but needs to be integrated into the whole public health view when data is being collected. In addition, the Department of Public Health has many areas of focus that are broad and don't just apply to occupational health. Asthma covers many areas, violence covers many areas, but occupational health needs to be integrated into these health areas so that these issues can be addressed. And lastly, again I just want to emphasize this link to the community health centers, this critical role that the Department of Public Health plays, addressing this enormous gap in resources that are available to these health centers to be able to address occupational health issues, to be able to ensure that they get into the Worker's Comp. system, which again is an enormous financial burden and toll for families. Thank you so much for this opportunity."

After, the 10 minute break, that allowed Senator Chandler to address the Council. Dr. David and Ms. Goldstein-Gelb returned to the Council to answer questions. Council Member Lucilia Prates Ramos noted, "I would just like to applaud you on the work that you have done. You know, issues that concern

immigrants are very dear to my heart, because I spent most of my life working with them and I am an immigrant myself. And so when you recommend that integration of occupational health take place, that screenings and surveys be part of the agenda of the Department of Public Health, I think that is a great recommendation, and you know, as you made your presentation, I look at how this is so complex and multi-layered, because when we are talking about some of these individuals who have been hurt, we are talking about individuals who may have authority to work and may not; and, you know, employers are then faced with sanctions, because when you speak of relying on partnering with communities, I mean one logical place to partner with would be the employer, let's educate these employers, you know, let's get this information out and that reaches these limited English proficient populations, employers are going to be hesitant to do that, to play that game, because they are not supposed to be hiring some of these people, correct, and so it raises all sorts of issues, and also some questions for me...When you talk about the emotional impact and the health impact on a family and communities. I mean it impacts the community at large a lot...How do we reach these people and how do we speak with them and how do we educate them is a real challenge, and it's a challenge that I would really echo in your recommendations and to really engage the Department of Public Health in working closely with community-based organizations, places of worship, the healthcare centers that you spoke of, but it is a real problem in our immigrant communities, I just want to echo some of your words and your concerns and thank you and applaud you for the work you are doing."

Council Member Rivera spoke about a friend of his who was injured at work, however his friend did not report the incident because his company gets a bonus for having no injuries in a year. Discussion followed by Dr. Davis and Ms. Goldstein-Gelb. Please see the verbatim transcript for full discussion. Ms. Goldstein-Gelb noted that employers should be fined for being in violation of the record-keeping laws and further for not posting information that their employees are entitled to Workers Compensation and she noted also that there is very little penalty for employers who discourage workers from reporting an incident.

Dr. Davis noted that Massachusetts is a Federal OSHA state; OSHA enforces health and safety standards in the private sector (no coverage for those in the public sector) in high risk industries. Employers are required to keep logs of work-related illnesses and injuries that require more than first-aid treatment or result in any restricted time or days away from work. The log data is collected by the federal Bureau of Labor Statistics in an annual survey. OSHA also collects the summary incident page from most employers. Dr. Davis noted further that only about 30 to 40 percent of work-related fatalities come under OSHA because OSHA doesn't deal with the public sector, the self-employed, on the road motor vehicles or violence related deaths.

Discussion continued by the Members, please see the verbatim transcript for further detail. Dr. Woodward asked, "Is there additional information that would have significant public health impact, if we had a better collection and reporting system and investigation system. Dr. David said that the inclusion of occupational information in the electronic health record of patients would have impact and improvements to the Worker's Compensation Data base would help.

Chairman Auerbach noted that it is unusual for a state health department to have a focused unit on occupational surveillance because there is no state funding for it. He said in part, "It is only due to the ingenuity and resourcefulness of Dr. Davis and her staff in terms of writing federal grants and other grants to sustain staffing that it exists."

Mr. Lanzikos added, "It strikes me that the Commonwealth, through its purchase of service contracting system, is responsible for the employment of tens of thousands if not hundreds of thousands of workers who come from these subpopulations that are experiencing these disparities, one sector is healthcare and personal care workers." He also mentioned homemakers and home health aids. "Since the Commonwealth is providing the funding, it has a lot of clout there. I am not sure about my agency that I operate, which receives millions of dollars of contracts that we then subcontract out. I am not sure we have the proper emphasis on workplace safety." He suggested that the EOHHS agencies make sure there are proper educational and safety safeguards and reporting mechanisms. Chair Auerbach said that it was a good idea.

No Vote / Information Only

The meeting adjourned at 12:00 p.m.

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John Auerbach, Chair

LMH